Remarks

The Advisory Action, mailed August 12, 2003, has been received and reviewed. In addition to the entry and consideration of the Amendment and Response, previously filed on July 25, 2003, the following remarks are provided for consideration by the Examiner. Reconsideration and withdrawal of the rejections are respectfully requested.

Election/Restriction

For reasons of record in the Amendment and Response, mailed July 25, 2003, Applicants continue to traverse the Election of Species Requirement, mailed May 1, 2002. Further, Applicants request clarification as to the scope of the claims currently under examination.

The 35 U.S.C. §112, First Paragraph, Enablement Rejection

In the Advisory Action, mailed August 12, 2003, the Examiner, "acknowledged that immunosuppressants can be administered after transplantation, however there is no immunosuppressive therapy for avoiding the reaction to cross species transplantation of cells into the gastrointestinal tract." Applicants respectfully disagree. Applicants submit that methods of immunosuppression are well known and widely applied by the skilled artisan. Applicants direct the Examiner to Low et al., "Immunobiology of Neural Xenotransplantation," in *Neural Transplantation Methods* Edited by Dunnett, Boulton and Baker; Humana Press 2000:503-541 (a copy of which was provided as Exhibit A in the Amendment and Response, mailed July 25, 2003) for a more complete discussion of immunosuppressive agents and therapies that are particularly applicable to neural xenotransplantation. Applicants submit that such widely known immunosuppressive methods will prevent the rejection of neural stem cells implanted into the gastrointestinal tract. The Examiner is invited to provide reasoned arguments and evidence to support his opinion that well known methods of immunosuppression are not applicable to the gastrointestinal tract.

Further, Applicants submit that the present specification exemplifies the successful xenogeneic transplantation of rat neural stem cells into the gastrointestinal wall of mice. See the Examples, page 13, lines 12-30, page 14, lines 8-12 and Figure 4.

In the Advisory Action, mailed August 12, 2003, the Examiner maintained that the specification provides inadequate "specific guidance for implanting cells to the gastrointestinal tract," stated that such methods are not well known, and further stated that the "Examiner is unaware of any teachings in the prior art for successfully implanting stem cells into the gastrointestinal tract." Applicants respectfully submit that the Examiner has mischaracterised the Applicants' arguments. Applicants have never submitted that the prior art teaches methods for the implantation of *stem* cells into the gastrointestinal tract. Rather, Applicants submit that methods for the implantation of cells, in general, into the gastrointestinal tract are well. Further, Applicants direct the Examiner to the specification itself, for guidance on the implantation of stem cells into the gastrointestinal tract (see, for example, page 13, lines 18-19).

In the Advisory Action, mailed August 12, 2003, the Examiner stated "with respect to the working example, it is unclear if the -/- NOS mouse represents any specific condition or disease. While the animal presents with a particular phenotype, it is not clear if any naturally occurring condition results from a lack of NOS formation." Applicants would like to point out that the lack of NOS, for example, due to the loss of nitric-oxide producing neurons, is well known in a variety of naturally occurring conditions. As discussed in the specification, "[i]n achalasia, Hirshsprung's disease, and congenital pyloric stenosis, loss of nitric oxide-producing neurons is well documented. This nitronergic loss leads to the inability of the gastrointestinal (GI) smooth muscle to relax, resulting in severe motility disorders" (page 1, lines 17-20).

Applicants respectfully submit that the specification provides adequate teaching and guidance for the claimed methods. Reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. §112, first paragraph, is respectfully requested.

Summary

It is respectfully submitted that the pending claims 21-27 and 31-45 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
Pasricha et al.

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August 27, 2003
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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, Mail Stop RCE, P.O. Box 1450, Alexandria, VA 22313-1450, on this 27th day of August, 2003, at 2:21pm (Central Time).

By: Sara E. Olson
Name: Sara E. OLSON

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